

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/902,176	SCHREIBER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sally A. Sakelaris	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/23/2005.
2. ☒ The allowed claim(s) is/are 12.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                   |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>6/21/2005</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>1/25/02 &amp; 2/17/05</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material  | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                          |
|   | 9. <input type="checkbox"/> Other _____.  |

***EXAMINER'S AMENDMENT***

Authorization for this examiner's amendment was given in a telephone interview with Melissa Schwaller on 6/21/2005.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Please delete present claim 12 and insert the following claim:

12. A method of diagnosis comprising detecting homozygosity for an A to G transition at position 168 in exon 2 of a gene coding for a TNF Receptor II wherein homozygosity for a guanine is detected in non-responders to anti-TNF therapy wherein a TNF-binding protein interferes with TNF binding to the TNF Receptor II, further wherein the TNF-binding protein that interferes with TNF binding to a TNF Receptor II is infliximab, and the anti-TNF therapy is therapy of Crohn's disease.

***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance:

The present invention is found to be allowable subject matter as its presentation of a method of detecting non-responders to infliximab anti-TNF therapy, through detection of homozygosity for a polymorphism at position 168 in exon 2 of a gene coding for a TNF Receptor II represents a contribution over the prior art that lacks any such method of detection.

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The closest prior art made of record is as follows:

Pantelidis et al(Tissue Antigens 1999: 54:585-591) teach polymorphic analysis of the high-affinity tumor necrosis factor receptor 2 and specifically those polymorphisms located in exons 4, 6, 9, and 10. Louis et al.(Clin. Exp. Immunol. 2000: 119, 64-68) teach that a polymorphism in the promoter of TNF gene(-308) may play a role in the behavior of Crohn's disease and seems to be associated with steroid-dependent disease and to a lesser extent with fistulizing and colonic disease.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 571-272-0748.

The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

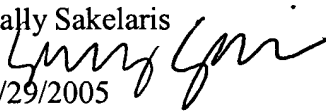
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris

6/29/2005



**W. Gary Jones**  
**Supervisory Patent Examiner**  
**Technology Center 1600**